



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES**MEMORANDUM**OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

Date: 20-April-2005

Subject: (2,4-Dichlorophenoxy)acetic acid (2,4-D acid) and 3,6-Dichlorophenoxyacetic acid (Dicamba Acid) in/on Pastures, Rangeland, and Grass (hay or silage); Sorghum; Wheat; and Cotton (preplant) and for Postharvest (fallow, crop stubble, and set aside acres); Noncrop Area; and Forest Management Purposes. Summary of Analytical Chemistry and Residue Data.

DP Barcodes: D313211

Registration: 42750-RNN - BWII

PC Code: 2,4-D - 030001
Dicamba - 029801

Decision #: 351949

MRID Nos.: none

From: Tom Bloem, Chemist *Tom Bloem*
Registration Action Branch 1, Health Effects Division (RAB1/HED; 7509C)

Through: PV Shah, Ph.D., Branch Senior Scientist *P.V. Shah*
RAB1/HED (7509C)

To: Joanne Miller/Dianne Morgan; RM 23
Registration Division (7505C)

Albaugh, Inc (Ankeny, IA) is requesting registration for application of BWII (EPA Reg. No. 42750-xxx) to pastures, rangeland, and grass; sorghum; wheat; and cotton (preplant) and for postharvest (fallow, crop stubble, and set aside acres); noncrop area; and forest management purposes. BWII is a new liquid formulation (type not indicated) containing 1.8 lbs dicamba acid per gallon and 2.4 lbs 2,4-D acid per gallon. In support of this request, the petitioner cites the currently-registered Outlaw™ label (EPA Reg. No. 42750-68) which contains 1.09 lbs dicamba acid per gallon and 1.45 lbs 2,4-D acid per gallon (present as the 2-ethylhexyl ester of 2,4-D). The petitioner states that the application scenarios included in BWII are similar to those included on the Outlaw™ label with the exception of substituting the 2,4-D acid for the 2,4-D ester.

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Executive Summary

Provided the petitioner submits a revised Section B as specified below and agrees to submit cotton gin byproduct residue data, HED concludes that registration of the BWII label is appropriate. With the submission of an acceptable Revised Section B, the proposed application scenarios will be nearly identical to the registered application scenarios (inconsequential differences in application rate) and the currently-established plant/livestock 2,4-D (40 CFR 180.142) and dicamba (40 CFR 180.227) tolerances are sufficient to cover the proposed uses.

• Submission of a revised Section B with the following changes:

- the statement "between crop applications/fallow systems" in the pasture, rangeland, and grass (hay and silage) section amended to "fallow systems"
- addition of a statement prohibiting tank mixing BWII with products which contain 2,4-D and/or dicamba; alternately, the petitioner may include instructions indicating that when tank mixing BWII with products which contain dicamba and/or 2,4-D, the total application rate of 2,4-D and/or dicamba in lbs ai/acre must conform to the lowest of the two labeled rates
- maximum single application rate to noncrop areas amended to indicate 1.45 lbs 2,4-D acid per acre and 1.09 lbs dicamba acid per acre
- following application at rates >0.8 lb dicamba acid per acre, only the following crops may be rotated (petitioner may specify the plantback intervals (PBIs) for these crops): corn, soybeans, cotton, wheat, barley, oats, grass pasture and hay or rangeland, sorghum, asparagus, and sugarcane
- the cotton preplant application scenario amended to specify rates of 0.33 lb 2,4-D acid per acre and 0.25 lb dicamba acid per acre and a preplant interval of 21 days[§]

- cotton gin byproduct residue data (n=6; 3 each conducted with stripper and picker harvesters; concentrated in USEPA regions 4, 8, and 10)[§]

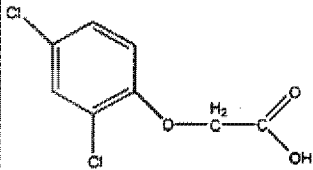
§ HED is requesting that the petitioner alter the proposed cotton preplant application scenario to conform with the HED-approved rate; as a condition of this registration, HED requested cotton gin byproduct dicamba residue data (D220430, F. Griffith, 2-May-1996; D228694, S. Chun, 25-Jun-1998; D249098, W. Donovan, 13-Oct-1998).

If the petitioner wishes to register the proposed rate, then cotton gin byproduct and cottonseed dicamba residue data should be submitted reflecting the currently-registered dicamba fall pre-plant application scenario (2.0 lbs dicamba acid per acre; cotton planted the following spring) and the proposed spring application scenario (1 x 0.88 lb dicamba acid per acre; 30 days prior to planting).

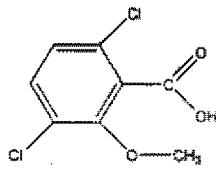
Detailed Considerations

Background

2,4-D: 2,4-D is generally used as a selective postemergence herbicide for the control of certain broadleaf weed species in a variety of crops and may also be used as a plant growth regulator or fungicide. 2,4-D mimics the activity of auxins which are natural plant hormones that regulate plant growth and are under direct metabolic control by the plant. At low concentrations, auxins promote normal growth and development. However, at abnormally high concentrations, auxins inhibit plant growth.

Table 1: Nomenclature of Test Compound	
Structure	
Common name	2,4-D
Company experimental names	not applicable
IUPAC name	(2,4-dichlorophenoxy)acetic acid
CAS name	(2,4-dichlorophenoxy)acetic acid
CAS #	94-75-7

Dicamba: Dicamba is a member of the benzoic or arylaliphatic acids class of chemicals. These chemicals are considered growth hormone herbicides and move both from leaves to the terminal meristem of leaf, shoot, and root, and also move in the transpiration stream, permitting them to be soil applied. Their mode of action is thought to be interference in protein synthesis with resulting interference in cell formation (G.W. Ware, The Pesticide Book, 1994).

Table 1: Nomenclature of Test Compound	
Structure	
Common name	dicamba
Company experimental names	not applicable
IUPAC name	3,6-dichloro-o-anisic acid
CAS name	3,6-dichloro-2-methoxybenzoic acid
CAS #	1918-00-9

860.1200 Directions for Use

The petitioner is requesting registration of BWII (EPA Reg. No. 42750-xxx; 1.8 lbs dicamba acid per gallon and 2.4 lbs 2,4-D acid per gallon) to pastures, rangeland, and grass; sorghum; wheat; and cotton (preplant); and for postharvest (fallow, crop stubble, and set aside acres); noncrop area; and forest management purposes. In support of this request, the petitioner cites the currently-registered Outlaw™ label (EPA Reg. No. 42750-68; 1.09 lbs dicamba acid per gallon and 1.45 lbs 2,4-D acid per gallon; present as the 2-ethylhexyl ester of 2,4-D) and states that application scenarios included in BWII are similar to Outlaw™ with the exception of substituting the 2,4-D acid for the 2,4-D ester. Table 1 and the following paragraph summarize the proposed application scenarios.

Application through irrigation equipment and application in greenhouses is prohibited. Aerial (spray volumes of 3-10 gallons per acre) and ground (spot, banded, and broadcast; broadcast and banded spray volumes of 10-25 gallons per acre) applications are permitted. Spot applications in addition to banded or broadcast applications are prohibited. The addition of drift retardants, crop oil concentrates, non-ionic surfactants, and liquid fertilizer to the spray solution are acceptable. The following PBIs are included (days when the ground is frozen are to be excluded when counting the interval from application to planting): (1) application of ≤ 3.66 pints per acre (≤ 1.1 lbs 2,4-D acid per acre; ≤ 0.8 lb dicamba acid per acre) - for barley, oat, wheat, and other grass seedlings, the interval is 10 days per 0.66 pints per acre (0.20 lb 2,4-D acid per acre; 0.15 lb dicamba acid per acre); for all other crops, the interval between application and planting is 120 days; (2) for applications > 3.66 pints per acre but ≤ 4.75 pints per acre (1.1-1.4 lbs 2,4-D acid per acre; 0.8-1.1 lbs dicamba acid per acre) - for barley, oat, wheat, and other grass seedlings grown east of the Mississippi River, the interval between application and planting is 10 days per 0.66 pints per acre; for barley, oat, wheat, and other grass seedlings grown west of the Mississippi River, the interval between application and planting is 15 days per 0.66 pints per acre; for all other crops grown in areas with ≥ 30 inches of rainfall per year, the interval between application and planting is 120 days; for all other crops grown in areas with < 30 inches of rainfall per year, the interval between application and planting is 180 days.

Conclusions: HED notes that excluding instruction for preplant application to cotton and the proposed maximum single application rate to noncrop areas (see below), the proposed application scenarios on the BWII label are very similar to the application scenarios on the currently-registered Outlaw™ label (inconsequential difference in application rates were noted). Since dairy cattle typically graze in fenced areas for which there is a high level of farmer control, the 7-day grazing restriction for dairy cattle is considered practical and enforceable (2,4-D Residue Chemistry Reregistration Eligibility Document (RED), D309450, 12-Oct-2004). However, HED does not consider the restriction prohibiting livestock from grazing in treated fields within 30 days of slaughter practical or enforceable; HED notes that the 2,4-D Residue Chemistry RED (D309450, 12-Oct-2004) and the dicamba residue chemistry reviews associated with application to grass (D220430, F. Griffith, 2-May-1996; D228694, S. Chun, 25-Jun-1998; D249098, W. Donovan, 13-Oct-1998), reassessed/assessed the livestock tolerances assuming a 0-day grazing restriction. Therefore, the current tolerances adequately account for a 0-day pregrazing interval for meat cattle. HED requests that the following changes be made to the

Dicamba acid and 2,4-D acid

Summary of Analytical Chemistry and Residue Data

D313211

BWII label: - Confidential, Internal, and Deliberative

- the statement "between crop applications/fallow systems" in the pasture, rangeland, and grass (hay and silage) section amended to "fallow systems"
- since tank mixing BWII with products which contain 2,4-D and/or dicamba may lead to application rates above which those that are currently supported by magnitude of the residue data, HED request that the label be altered to include a statement prohibiting the tank mixing BWII with products which contain 2,4-D and/or dicamba; alternately, the petitioner may include instructions indicating that when tank mixing BWII with products which contain 2,4-D and/or dicamba, the total application rate of 2,4-D and/or dicamba in lbs ai/acre must conform to the lowest of the two labeled rates
- the currently-registered Outlaw™ label indicates a maximum single application rate to noncrop areas of 1.45 lbs 2,4-D acid per acre and 1.09 lbs dicamba acid per acre; HED requests that the BWII label be amended to conform with this maximum
- following application at rates >0.8 lb dicamba acid per acre, only the following crops may be rotated (petitioner may specify the PBIs for these crops): corn, soybeans, cotton, wheat, barley, oats, grass pasture and hay or rangeland, sorghum, asparagus, and sugarcane
- the cotton preplant application scenario amended to specify rates of 0.33 lb 2,4-D acid per acre and 0.25 lb dicamba acid per acre and a preplant interval of 21 days[§]

§ HED is requesting that the petitioner alter the proposed cotton preplant application scenario to conform with the HED-approved rate (D220430, F. Griffith, 2-May-1996; D228694, S. Chun, 25-Jun-1998; D249098, W. Donovan, 13-Oct-1998).

If the petitioner wishes to register the proposed rate, then cotton gin byproduct and cottonseed dicamba residue data should be submitted reflecting the currently-registered dicamba fall pre-plant application scenario (2.0 lbs dicamba acid per acre; cotton planted the following spring) and the proposed spring application scenario (1 x 0.88 lb dicamba acid per acre; 30 days prior to planting).

860.1300 Nature of the Residue - Plants

Dicamba: The nature of the residue in plants is adequately understood (D220469, F. Griffith, 2-May-1996). The residues to be regulated in barley, corn, cotton, oats, wheat, and grasses are dicamba and its 5-OH metabolite (3,6-dichloro-5-hydroxy-o-anisic acid); in asparagus, the residues to be regulated are dicamba and DCSA (3,6-dichloro-o-anisic acid); and in soybeans and aspirated grain fractions, the residues to be regulated are dicamba, 5-OH dicamba and DCSA.

2,4-D: The nature of the residue in plants is understood based on lemon, potato, and wheat metabolism studies. The HED Metabolism Assessment Review Committee (MARC) determined that the residue of concern in plants for the tolerance expression and for risk assessment is 2,4-D *per se* in both the free and conjugated forms (D293119, W. Hazel and L. Taylor, 3-Dec-2003).

860.1300 Nature of the Residue - Livestock

Dicamba: The nature of the residue in ruminants and poultry is adequately understood. In ruminants the metabolic pathway is the same as in asparagus and soybeans which is demethylation and formation of the DCSA metabolite. The same basic metabolic pathway exist in poultry; however there is a minor pathway producing a small amount of 2-amino-3,6-dichlorophenol found in poultry liver. The residues to be regulated in livestock are dicamba and its DCSA metabolite (D204482, L. Cheng, 7-Mar-1996,).

2,4-D: The nature of the residue in ruminants and poultry is adequately understood. The MARC determined that the residue of concern in livestock for the tolerance expression and for risk assessment is 2,4-D *per se* in both the free and conjugated forms (D293119, W. Hazel and L. Taylor, 3-Dec-2003).

OPPTS GLN 860.1340: Residue Analytical Methods

The petitioner has not submitted any residue data with the current petition and has not proposed any new 2,4-D or dicamba tolerances. In addition, HED is not recommending for the establishment of new tolerances. Therefore, a discussion concerning residue analytical methods is irrelevant.

OPPTS GLN 860.1360: Multiresidue Method

Dicamba: The Food and Drug Administration (FDA) Pesticide Analytical Manual (PAM) Volume I Appendix II Table 201-D, shows that dicamba is partially recovered (71 - 76%) using Protocol B.

2,4-D: The 10/97 edition of FDA PAM Volume I Appendix I indicates that 2,4-D is partially recovered (50-80%) using Multiresidue Method Sections 402 E1 and 402 E2. Conjugated metabolites would not be determined by the FDA multiresidue methods.

OPPTS GLN 860.1380: Storage Stability Data

As no magnitude of the residue data were submitted with the current petition, a discussion concerning the stability of dicamba and 2,4-D in plants and livestock is irrelevant.

OPPTS GLN 860.1480 Meat/Milk/Poultry/Eggs; GLN 860.1500: Crop Field Trials; and GLN 860.1520: Processed Food/Feed

Provided the petitioner submits a revised Section B as specified in OPPTS 860.1200 Directions for Use Section, the proposed application instructions to food/feed crops, with the exception of a preplant-cotton application, are nearly identical to the application instructions on the currently-registered Outlaw™ label (inconsequential variations in application rates) with the only difference being 2,4-D present as the acid in the BWII label and as an ethylhexyl ester in the Outlaw™ label. The following paragraphs pertain to the magnitude of 2,4-D acid and dicamba acid residues in/on the proposed crops.

2,4-D: The Residue Chemistry RED stated that for purposes of setting tolerances, the three classes of 2,4-D (acid, amine salts, and esters) are not equivalent (D309450, 12-Oct-2004). The RED went on to say that the residue data conducted with the amine salt or ester forms may be used in support of the acid. Since the ester is currently registered and since the proposed application scenarios (excluding cotton; see below) are identical to currently-registered application scenarios, HED concludes that the currently-established tolerances are acceptable.

The residue chemistry RED stated that the available confined rotational crop study conducted at 2.17 lbs 2,4-D per acre (1.1x the maximum rate for all registered/proposed crops; 2.2x the cotton rate) indicate that additional field data are not required and no rotational crop tolerances/PBIs are needed (D309450, 12-Oct-2004). Based on this conclusion, the proposed preplant application of 2,4-D to cotton is acceptable. No additional tolerances are required.

Dicamba: Since the proposed application scenarios (excluding cotton; see below) are identical to currently-registered application scenarios, HED concludes that the currently-established tolerances are acceptable.

The petitioner initially received registration for preplant application of dicamba sodium salt to cotton as follows (Banvel SGF®; EPA Reg. No. 55497-28): broadcast application at 2 lbs ai/acre after harvest and before a killing frost (cotton may be planted in the spring following application made the previous year). Following this, HED approved the following addition preplant application of dicamba sodium salt to cotton (D220430, F. Griffith, 2-May-1996; D228694, S. Chun, 25-Jun-1998; D249098, W. Donovan, 13-Oct-1998): broadcast application at 0.25 lb ai/acre 21 days prior to planting cotton. As part of the latter registration, HED requested cotton gin byproduct residue data reflecting the 2 lbs ai/acre post-harvest application (when this application scenario was approved, cotton gin byproduct was not considered a feed commodity and residue data were not submitted; cotton gin byproduct residue data reflecting the 0.25 lb ai/acre application 21 days prior to harvest are available). As of the writing of this document, HED has not received the cotton gin byproduct residue data. Currently, the petitioner is requesting preplant application of dicamba acid to cotton at 0.22-0.82 lb ai/acre 30 days prior to planting.

Dicamba acid and 2,4-D acid

Summary of Analytical Chemistry and Residue Data

D313211

Provided the preplant application scenario for cotton is altered to conform with previously agreed rate (0.25 lb dicamba acid per acre and a preplant interval of 21 days) and the petitioner agrees to submit the requested cotton gin byproduct residue data (D220430, F. Griffith, 2-May-1996; D228694, S. Chun, 25-Jun-1998; D249098, W. Donovan, 13-Oct-1998), HED concludes that preplant application to cotton is acceptable. If the petitioner wishes to register the proposed rate, then cotton gin byproduct and cottonseed residue data reflecting the currently-registered dicamba fall pre-plant application scenario (2.0 lbs dicamba acid per acre; cotton planted the following spring) and the proposed spring application scenario (1 x 0.88 lb dicamba acid per acre; 30 days prior to planting) should be submitted.

HED notes that dicamba cotton gin byproduct residue data are not currently available; therefore, the potential transfer of residues to livestock resulting from application to cotton is unknown. Since dicamba is currently registered for application to grass with forage and hay tolerances of 125 ppm and 200 ppm, respectively, HED concludes that the contribution of cotton gin byproduct to the livestock dietary burden will be minimal. Therefore, prohibiting the feeding of cotton gin byproduct to livestock prior to the submission and review of the residue data is unnecessary.

GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

2,4-D: The residue chemistry RED stated the following (D309450, 12-Oct-2004): the available confined rotational crop study conducted at 2.17 lbs 2,4-D per acre (1.1x the maximum proposed/registered rate) indicate that additional field data are not required and no rotational crop tolerances are necessary and no PBIs following 2,4-D application are needed. Therefore, the proposed rotational crop PBIs are acceptable.

Dicamba: HED has previously concluded that the PBIs provided in Table 2 are appropriate for dicamba (D228694, S. Chun, 24-Jun-1998). Based on these conclusions and the proposed application rate, HED requests that the petitioner alter the label to indicate that following application at rates >0.8 lb dicamba acid per acre, only the following crops may be rotated (petitioner may specify the PBIs for these crops): corn, soybeans, cotton, wheat, barley, oats, grass pasture and hay or rangeland, sorghum, asparagus, and sugarcane.

Table 2: Appropriate PBIs for Dicamba (D228694, S. Chun, 24-Jun-1998)	
Application Rate	Rotational Restrictions
0.75 or less lb dicamba acid per acre	After 120 days from time of application: no rotational cropping restrictions apply. Planting within 120 days of application: only rotate to crops below.
0.75 to 2.0 lb dicamba acid per acre	Rotate to the following crops only: corn, soybeans, cotton, wheat, barley, oats, grass pasture and hay or rangeland, sorghum, asparagus, sugarcane.

Attachment 1: Chemical Structures

RDI: RAB1 chemists - 20-April-2005

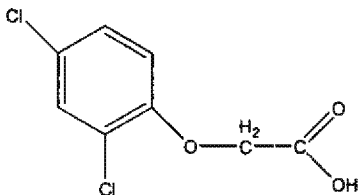
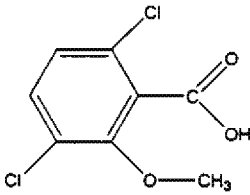
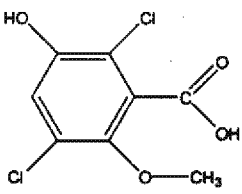
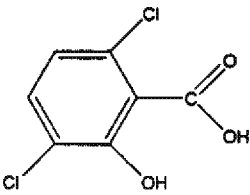
T. Bloem:806R:CM#2:(703)605-0217:7590C

Dicamba acid and 2,4-D acid

Summary of Analytical Chemistry and Residue Data

D313211

Attachment #1 ~~Confidential, Internal, and Deliberative~~

Compound	Structure
2,4-D acid (2,4-dichlorophenoxy)acetic acid	
dicamba 3,6-dichloro-2-methoxybenzoic acid	
5-OH dicamba 3,6-dichloro-5-hydroxy-o-anisic acid	
DCSA 3,6-dichloro-o-anisic acid	



13544



R109694

Chemical: 2-4,D

PC Code: 030001
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Memo Date: 04/20/2005
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Accession Number: 412-05-0096

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